

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON**

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION THIS DOCUMENT RELATES TO: ALL WAVE 2 PLAINTIFFS LISTED IN EXHIBIT 1 TO PLAINTIFFS' MOTION	Master File No. 2:12-MD-02327 MDL 2327 JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
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**RESPONSE IN OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE
OPINIONS AND TESTIMONY OF TIMOTHY BRIAN MCKINNEY, M.D.**

As a threshold matter, Plaintiffs have incorporated by reference their *Daubert* challenge to Dr. McKinney's opinions filed in Wave 1. *See* Pls.' Mem. (Dkt. 2443) at 1 (incorporating Plaintiffs' Wave 1 McKinney motion and memorandum, Dkts. 2001 and 2002, respectively). Defendants Ethicon, Inc. and Johnson & Johnson (Ethicon), in turn, adopt their response to Plaintiffs' Wave 1 motion (Dkt. 2139).

Plaintiffs nonetheless raise additional arguments not addressed in their Wave 1 motion and Ethicon responds to those arguments here. In particular, Plaintiffs seek to broadly exclude several of Dr. McKinney's opinions addressing alternative procedures, various studies, and his experience with TTVT products and their warnings. They claim that these opinions are irrelevant, prejudicial, speculative, or otherwise outside his area of expertise. Plaintiffs' motion should be denied because:

- **Dr. McKinney's native-tissue opinions are relevant.** Dr. McKinney's opinions are not limited to TTV products, but include prolapse products as well. Indeed, Dr. McKinney has authored two reports—one for prolapse products and another for TTV products.
- **It is premature to exclude isolated statements taken out of context.** Plaintiffs seek wholesale exclusion of certain "Gold Standard" and "lowest level of evidence" statements made by Dr. McKinney, claiming they are unsupported. Merely taking certain statements out of context and in isolation, however, does not show that the statements are unsupported. Until explained at trial, it is premature to wholly exclude these statements.
- **Dr. McKinney's opinions drawn from his review of the literature are relevant.** Dr. McKinney is a pioneer in the field of urogynecology and his opinions are based, in part, on his extensive review of the relevant medical literature. Plaintiffs merely disagree with the conclusions Dr. McKinney draws from that review, which is an issue better suited for cross-examination, and not a basis for exclusion.
- **The challenged IFU opinion is not an "adequacy" opinion.** The IFU opinions elicited addressed IFUs in general, not any particular product's IFU specifically, and had nothing to do with the "adequacy" of any particular IFU. Even so, McKinney's extensive training, experience, and review of the relevant medical literature qualify him to offer the general IFU opinions challenged.
- **Dr. McKinney will not offer opinions on the 510(k) process.** Dr. McKinney's plaintiff-initiated 510(k) testimony does not amount to a regulatory opinion, which he is not rendering here.

Plaintiffs' challenges to Dr. McKinney's opinions are meritless under Rules 702 and 403, and *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993). Their motion should be denied.

ARGUMENTS AND AUTHORITIES

I. Dr. McKinney's opinions are relevant and admissible.

A. Dr. McKinney's opinions regarding native tissue and prolapse repairs are covered by his Rule 26 reports.

Plaintiffs argue that Dr. McKinney's opinions on native tissue prolapse repairs, including his interpretation of the SISTER clinical trial, are irrelevant because his expert report offers opinions only as to TTV products, which are treatment options for stress urinary incontinence—

not prolapse. Pls.’ Mem. (Dkt. 2443) at 5-6. Plaintiffs, however, attached and referenced only Dr. McKinney’s TVT Report to their motion. *See* Ex. B to Pls.’ Mot. (Dkt. 2438-3), McKinney TVT Report. Plaintiffs failed to consider Dr. McKinney’s Prolene Soft Report—which Ethicon submitted in both Wave 1 and Wave 2. *See* Ex. 1, McKinney Prolene Soft Report. Dr. McKinney’s Prolene Soft Report covers treatment options for prolapse. *See, e.g., id.* at 19-21. Therefore, his opinions on native tissue prolapse repairs and the SISTER clinical trial are relevant on that basis.

B. Even if Dr. McKinney’s conclusions regarding the Cochrane Review and Nilsson study make his opinions “inaccurate”—and they do not—that is not a proper basis on which to exclude his testimony.

Plaintiffs take issue with Dr. McKinney’s review and interpretation of the 2015 Cochrane Review and Nilsson study, and the conclusions he reached based upon that review. They argue that Dr. McKinney’s conclusions are inaccurate and irrelevant, and therefore that they should be excluded. Pls.’ Mem. (Dkt. 2443) at 6-9.

These challenges simply are not part of a proper *Daubert* analysis. Indeed, an expert’s interpretation of a study is a matter for cross-examination, not exclusion. *Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 552 (S.D.W. Va. 2014) (“As the gatekeeper of expert testimony, [the Court] need not concern [it]self with the ‘correctness of the expert’s conclusions’ and should instead focus on the ‘soundness of his methodology.’” (quoting *Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1318 (9th Cir. 1995))). Indeed, even if the medical literature is “not seamlessly align[ed]” with an expert’s interpretation of a study, his methodology is not rendered unreliable as long as his interpretation is plausible. *Hovey v. Cook Inc.*, No. 2:13-cv-18900, 2015 WL 1405565, at *5 (S.D.W. Va. Mar. 26, 2015); *see also United States v. Moreland*, 437 F.3d 424, 431 (4th Cir. 2006) (“The court need not determine that the proffered expert testimony is irrefutable or certainly correct.”).

Plaintiffs also claim that Dr. McKinney should be precluded from offering any opinions based on the Nilsson study because his deposition testimony “undermines” his conclusion. Pls.’ Mem. (Dkt. 2443) at 8. They then excerpt the purported “undermining” testimony in an attempt to attack Dr. McKinney’s conclusions. *Id.* Whatever they were trying to show with this testimony, “undermining” it is not. But even so, any discrepancies between an expert’s report and testimony in deposition is a matter for cross-examination, not a basis for exclusion. *Eghnayem v. Boston Scientific Corp.*, 57 F. Supp. 3d 658, 678 (S.D.W. Va. 2014).

At bottom, Plaintiffs are challenging Dr. McKinney’s conclusions, not his methodology. As *Daubert* and this Court have made clear, challenging the accuracy of an expert’s conclusions is not a proper basis for exclusion under *Daubert*; rather, these challenges “are better suited for cross-examination.” *Tyree*, 54 F. Supp. 3d at 532; *Wise v. C.R. Bard, Inc.*, No. 2:12-cv-01378, 2015 WL 521202, at *21 (S.D.W. Va. Feb. 7, 2015) (“The plaintiffs, instead, focus their arguments on why Dr. Clark’s ultimate conclusion—that degradation does not occur—is wrong according to other sources. However, under *Daubert*, the court is not to decide whether an opinion is scientifically correct; it is to evaluate the method a proffered expert uses in reach that opinion.”). Because Plaintiffs’ “relevancy” challenges here go only to Dr. McKinney’s conclusions—not his methodology—their arguments fall outside the scope of a *Daubert* analysis and should be rejected.

C. Isolated statements taken out of context do not make those statements inadmissible.

Plaintiffs claim Dr. McKinney’s “lowest level of evidence,” “Gold Standard,” and “escape from the dark ages” statements that are contained in his report are unsupported, prejudicial, and should be excluded. *See* Pls.’ Mem. (Dkt. 2443) at 9-10. Without more, however, this is no basis for exclusion. Until used in context or otherwise explained, it would be premature

to wholesale exclude these statements. As this Court recently noted, a party's use of "out-of-context statements," among other practices, "creates the perfect storm of obfuscation" that compelled this Court to "reserv[e] ruling until the reliability of an expert's opinion may be evaluated at trial." *Trevino v. Boston Scientific Corp.*, No. 2:13-cv-01617, 2016 WL 2939521, at *1 (S.D.W. Va. May 19, 2016).

But even if otherwise, Plaintiffs' "unsupported" argument is baseless. Dr. McKinney explains that he considers "case reports and case series" to be the lowest level of evidence. Ex. B to Pls.' Mot. (Dkt. 2438-3), McKinney TTV Report at 10. This is not an unsupported opinion in the scientific community. Indeed, case reports merely report an anecdotal individual case uncontrolled for error or bias; a case series is merely a compilation of similarly uncontrolled case reports. *Tompkins v. Sec'y of Dep't of Health & Human Servs.*, No. 10-261, 2013 WL 3498652, at *24 (Fed. Cl. Ct. June 21, 2013). In the hierarchy of scientific evidence, the scientific community considers these two forms of evidence at the bottom. *Id.*; *see also* FED. JUDICIAL CTR., REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 724 (3d ed. 2011) (noting that, in determining medical causation, case reports "are at the bottom of the evidence hierarchy," largely because they lack controls); *see also* Ex. B to Pls.' Mot. (Dkt. 2438-3), McKinney TTV Report at 7 ("Case reports and case series are of limited value and do not address the incidence of complications or primary and secondary management.").

As for the "Gold Standard" statement, there is nothing unsupported about that statement when viewed in the context of Dr. McKinney's standard-of-care opinion. There, he explains the studies that support this statement and opinion, and the multitude of organizations that have studied and endorsed the TTV and TTV-O as not only safe and effective, but "recognized as the Gold Standard, standard of care, and first line and suitable surgical option to treat stress urinary

incontinence.” Ex. B to Pls.’ Mot. (Dkt. 2438-3), McKinney TTV Report at 7-8. Thus, Dr. McKinney’s “Gold Standard” statement and opinion is fully supported.

Viewed in context, as the statements contained in Dr. McKinney’s report should be, the statements Plaintiffs challenge are adequately supported. It would be premature to take these isolated statements out of the context they were offered and wholly exclude them. Plaintiffs’ argument to the contrary should be rejected.

II. Dr. McKinney’s opinions are based on his clinical experience and review of the medical literature—both well-accepted methodologies for formulating expert opinions.

A physician’s “knowledge, experience, and review of scientific literature provide sufficiently reliable bases for his opinions under *Daubert*.” *Eghnayem*, 57 F. Supp. 3d at 714. This Court in particular has made clear that a physician can draw upon his clinical experience and review of relevant literature to give an opinion on the safety and efficacy of polypropylene mesh products. *See Tyree*, 54 F. Supp. 3d at 585 (finding that a urologist with extensive clinical experience and relying on peer-reviewed literature could opine on the safety and efficacy of polypropylene mesh products).

Plaintiffs, however, criticize several of Dr. McKinney’s opinions as being infirm because they are unsupported by the medical literature or his experience. First, they claim that Dr. McKinney could not know “frustrations” of surgeons. Pls.’ Mem. (Dkt. 2443) at 11. Yet, Dr. McKinney—a pioneer in the field of urogynecology—has been a leader in this field. He has taught hundreds of courses on pelvic reconstruction, and indeed started a company that has taught others on unembalmed cadavers to “to do a more anatomical repair.” Ex. B to Pls.’ Mot. (Dkt. 2438-3), McKinney TTV Report at 2, 4. He has conducted research, published widely, given numerous presentations, and written chapters in textbooks. *Id.* at 2-3. Given this breadth of experience and discourse with his colleagues, it defies common sense that he would not know

common frustrations among those in his field. The frustrations he and his colleagues face as a pelvic-floor surgeon is well within his expertise.

Second, Plaintiffs take issue with Dr. McKinney's statement that surgery is the "most definitive treatment" for stress urinary incontinency. They claim it is "vague and ambiguous," and its meaning is unclear. Pls.' Mem. (Dkt. 2443) at 11. Certainly taking a statement out of context and in isolation may make any statement's meaning unclear. Viewed in context, Dr. McKinney is giving a background of the treatment for stress urinary incontinence and goes on to list several surgical procedures performed as treatment, of which implanting TVT products is included. *See Ex. B to Pls.' Mot.* (Dkt. 2438-3), McKinney TVT Report at 5-6. There is no per se "opinion" attached to that statement other than it gives background for the opinions ultimately expressed.

Third, Plaintiffs claim Dr. McKinney's opinion that TVT products have the "longest and broadest track record of safe and effective use" should be excluded because his reliance on the SISTER clinical trial, Cochrane Review, and Nilsson study is "fundamentally flawed." Pls.' Mem. (Dkt. 2443) at 11. But, as already discussed, these criticisms go to Dr. McKinney's conclusions—not his methodology—which is not a proper basis for exclusion. *See supra* Part I.B.

And lastly, they argue that Dr. McKinney's pore-size opinion is unsupported, which they claim he essentially conceded in deposition. Pls.' Mem. (Dkt. 2443) at 11-12. Plaintiffs misstate Dr. McKinney's testimony and misunderstand the analysis for admissibility under *Daubert*. The testimony excerpted on page 11 of their memorandum merely shows that Dr. McKinney did not conduct a search of the literature "specific to vaginal mesh pore size." *Id.*; *see also* Ex. D to Pls.' Mot. (Dkt. 2438-5), McKinney 6/29/16 Dep. Tr. 34:22-35:1. It does not show that his pore-size

opinions are unsupported. In fact, a complete reading of Dr. McKinney’s deposition shows that he based his pore-size opinions on a review of two studies—the Falconer and Ahmed studies. Ex. D to Pls.’ Mot. (Dkt. 2438-5), McKinney 6/29/16 Dep. Tr. 32:16-34:14.

Given that these opinions are based on Dr. McKinney’s review of relevant medical literature—an accepted scientific methodology—Plaintiffs’ challenge should be rejected. They merely disagree with the conclusions Dr. McKinney reached based on his review of this literature, which is not a basis for exclusion under *Daubert*. See *Eghnayem*, 57 F. Supp. 3d at 714.

III. Dr. McKinney’s IFU testimony is admissible.

Plaintiffs take issue with Dr. McKinney’s IFU testimony—elicited by Plaintiffs’ counsel—as to Dr. McKinney’s general perceptions about what should be included in an IFU and how an IFU is used by physicians in general. See Pls.’ Mem. (Dkt. 2443) at 14. Plaintiffs frame this argument as an “adequacy” argument, but the testimony Plaintiffs point to in their memorandum says nothing about IFU adequacy. Instead, Dr. McKinney is expressing his opinion, in response to Plaintiffs’ counsel’s questioning, about the “basic premise” of an IFU in general and how an IFU is used, or should be used, in practice. *Id.* Although “[d]octors are fully qualified to opine on the medical facts and science regarding the risks and benefits of drugs and to compare that knowledge with what was provided in the text of labeling and warnings” (*Winebarger v. Boston Scientific Corp.*, No. 2:13-cv-28892, 2015 WL 1887222, at *15 (S.D.W. Va. Apr. 24, 2015)), Dr. McKinney’s IFU testimony challenged by Plaintiffs here is not an “adequacy” opinion at all much less an opinion as to whether the IFUs at issue here, in particular, are adequate.

Plaintiffs’ reliance on this Court’s decision in *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589 (S.D.W. Va. 2013), does nothing to advance their argument. In that case, the Court addressed an

expert's qualifications to provide an opinion about what should have been included in a product's warnings. *Id.* at 611. The opinion testimony excerpted at page 14 of Plaintiffs' memorandum offers no such opinion. *In re C.R. Bard* is wholly irrelevant.

But even if Dr. McKinney's nonspecific, general IFU testimony can be construed as an "adequacy" opinion—and it is not—Dr. McKinney is well-qualified to render this opinion. As a pioneer in this field, he has performed thousands of mesh surgical procedures, taught others on proper surgical technique, and has widely published, presented, and conducted research in this area. *See Ex. B to Pls.' Mot.* (Dkt. 2438-3), McKinney TTV Report at 1; Ex. 1, McKinney Prolene Soft Report at 1. He has considerable experience from which to offer opinions about the "basic premise" of IFUs in general and how physicians in general use and rely on a product's IFU.

At bottom, Plaintiffs' challenge to Dr. McKinney's IFU opinions is baseless. He is sufficiently qualified to give the IFU testimony Plaintiffs challenge. Plaintiffs' IFU argument should be rejected.

IV. Dr. McKinney will not offer opinions on the 510(k) process.

Plaintiffs correctly note that Dr. McKinney did not offer opinions concerning the 510(k) clearance process in his Rule 26 report. Plaintiffs nonetheless questioned Dr. McKinney at length about his opinions on this issue at deposition. *Ex. D to Pls.' Mot.* (Dkt. 2438-5), McKinney 6/29/16 Dep. Tr. 29:18-31:20. Ethicon will not be offering these plaintiff-initiated opinions; thus, Plaintiffs' request for their exclusion is moot.

CONCLUSION

For the foregoing reasons, Ethicon respectfully asks this Court to deny Plaintiffs' motion.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on August 8, 2016, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

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